THE UNIVERSITY OF ZAMBIA

SCHOOL OF MEDICINE

ANAESTHETIC RELATED PERI-OPERATIVE COMPLICATIONS DURING CAESAREAN DELIVERY AT THE UNIVERSITY TEACHING HOSPITAL, LUSAKA, ZAMBIA.

DR. CHAKANA COLLINS (BSc.Hb, MBChB)

DISSERTATION SUBMITTED TO THE UNIVERSITY OF ZAMBIA IN PARTIAL FULLFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF MEDICINE IN ANAESTHESIA AND INTENSIVE CARE

The University of Zambia

Lusaka

2015

COPYRIGHT DECLARATION

By Dr Chakana Collins

2015

DECLARATION

I DR COLLINS CHAKANA HEREBY DECLARE THAT THIS DISSERTATION HEREIN PRESENTED FOR THE DEGREE OF MASTER IN ANAESTHESIA AND INTENSIVE CARE HAS NOT BEEN PREVIOUSLY SUBMITTED EITHER IN WHOLE OR IN PART FOR ANY OTHER DEGREE AT THIS OR ANY OTHER UNIVERSITY, NOR BEING CURRENTLY SUBMITTED FOR ANY OTHER DEGREE.

SIGNED

_____

Dr Chakana Collins

APPROVED BY_____

Dr Vwalika Bellington (supervisor)

STATEMENT

I HEREBY STATE THAT THIS DISSERTATION IS ENTIRELY THE RESULT OF MY OWN PERSONAL EFFORT. THE VARIOUS SOURCES TO WHICH I AM INDEBTED HAVE BEEN CLEARLY INDICATED IN THE BIBLIOGRAPHY AND ACKNOWLEDGEMNT.

SIGNED _____

Dr Chakana Collins

CERTIFICATE OF APPROVAL

THE DISSERTATION OF DR CHAKANA COLLINS IS APPROVED AS FULFILLING PART OF THE REQUIREMENT FOR THE AWARD OF THE DEGREE OF MASTER OF MEDICINE IN ANAESTHESIA AND INTENSIVE CARE BY THE UNIVERSITY OF ZAMBIA.

EXAMINER'S SIGNATURE DATE

_____ _____

_____ _____

_____ _____

ABSTRACT

Background: Caesarean deliveries are increasingly performed at the University Teaching Hospital (UTH), Lusaka, with a 2012 audit report indicating a rate of 17.8%. The procedure is a major surgical intervention and results in higher morbidity than vaginal delivery. Part of this morbidity and mortality during caesarean delivery is that resulting from the anaesthesia relating to the surgery. However, information on the extent of anaesthetic related complications associated with caesarean deliveries in low resource settings such as at UTH is lacking. This study endeavored to explore this aspect.

Objective: To determine the frequency of anaesthetic related perioperative complications during caesarean delivery at the UTH, Lusaka, Zambia

Study Design: A prospective observational study documenting the anaesthetic related complications in women undergoing caesarean delivery at UTH. Two hundred and forty six (246) consecutive parturients undergoing caesarean deliveries were enrolled in the study.

Methodology: All women who presented for caesarean delivery at UTH in Lusaka, Zambia from January 12, 2014 to July 12, 2014 and met the inclusion criteria were recruited into the study. Information on the patient and her management was obtained from the patient's medical records. Participants were followed up from the time they were taken into theatre, during the procedure until the time they left the recovery room post operatively, and any complication observed was documented. Hypotension, possible aspiration, failed intubation, conversion from spinal to general anaesthesia, severe hypoxemia and death were the main outcome measures. A descriptive analysis was performed. All significant variables were included in the final multivariable logistic model. All tests were set at 95% confidence interval (CI) and a P- value of <0.05 was considered statistically significant.

Results: No mortality was recorded out of the 246 parturients enrolled for the study. The average age was 28 years. Thirty-four cases (13.8%) received general anaesthetic while 212 cases (86.2%) had spinal anaesthetic. Obstructed labour 79 cases (32.1%) and previous caesarean sections 68 cases (27.6%) were among the indications for caesarean deliveries. Perioperative complications recorded included, 172 cases (69.9%) of hypotension, 6 cases (11.1%) had failed intubation, 5 cases (9.3%) possibly aspirated, 20 cases (9.4%) had failed spinal technique needing conversion to general anaesthetic, 6 cases (3.1%) had high spinal block. Severe hypoxemia intraoperatively and postoperatively was noted in 16 cases (6.5%) and 7 cases (2.8%) respectively. There were no statistically significant associations among the complications with age of parturients, ASA status, grade of anaesthetist, category of caesarean sections, indication for caesarean sections or gestational age. There was a significant association between Mallampati and failed intubation (p value= 0.012).

Conclusion: There are many anaesthetic related complications during caesarean sections occurring at UTH. Future studies are needed to solely look into factors contributing to each of the complication at UTH.

ACKNOWLEDGEMENT

I am acknowledging all the people that helped me from the time of proposal development, data collection, analysis and writing up of this dissertation.

I am particularly grateful to the following:

1. Professor John Kinnear and Dr. Bellington Vwalika, my supervisors for their invaluable relentless guidance and support.
2. Dr. Dylan Bould for his encouragement and support.
3. Dr Yusuf Ahmed for all his help.
4. My research assistants nurse Ireen Zulu and nurse Mercy Kopeka for their hard work during the collection of data.
5. All the members of staff in the Department of Anaesthesia and Intensive Care for their unrelenting help during data collection.
6. All the women that willfully participated in my study.

CONTENTS

LIST OF TABLES

ABBREVIATIONS

CEMD	Confidential Enquiry into Maternal deaths
BP	Blood pressure
CS	Caesarean section
UNZABREC	University of Zambia Biomedical Research Ethics Committee
UTH	University Teaching Hospital
SPSS	Statistical Package for Social Sciences
Hb	Hemoglobin
HIV	Human Immunodeficiency Virus
DM	Diabetes Mellitus
COA	Clinical officer anesthetist
MMed	Masters in medicine
Pg	Postgraduate
GPPF	Graduate Proposal Presenting Forum
Pt	Patient

DEDICATION

I dedicate this work of my dissertation to my best friend and wife Jean: Sweetheart you are my inspiration.

Chapter One

1.0 Introduction

Caesarean deliveries are increasingly performed in the University Teaching Hospital (UTH), Lusaka, with a study in 1982 reporting a rate of 7.5%.[1] Data from a 2012 audit report indicated a rate of 17.8 %. The procedure is a major surgical intervention that has an increased incidence of morbidity in comparison with vaginal delivery.[2] Part of the morbidity and mortality suffered from caesarean delivery is that resulting from the anaesthesia related to the surgery.[3,4,5,6] There is no data describing the anaesthesia associated morbidity and mortality at the University Teaching Hospital (UTH).

Anaesthesia has emerged as an additional risk factor in maternal deaths, and mortality associated with caesarean delivery has been described in several studies.[3,4,5,6] These include reports from Lome, Togo, with 12 anesthetic deaths out of 318 caesarean deliveries performed, a rate of 3.8%,[7] Nigeria, with 84 maternal deaths out of 2323 caesarean deliveries, with anaesthesia accounting for 6 (rate of 7.1%).[6] A study done in Kampala, Uganda, showed anaesthesia to be the direct cause of 24 maternal deaths in the 7 years reviewed,[4] and another study from Nigeria reported 9% of maternal mortality as attributable to anaesthesia.[5] Despite these alarming figures, anaesthesia as a cause of maternal morbidity and mortality remains largely underreported in underdeveloped countries.[6] Nonetheless, the number of case fatalities associated with anaesthesia remains small compared with those associated with avoidable obstetric factors.[6,7,8]

While most studies report mortality rates, many fail to address the rate of avoidable anaesthetic complications. These were defined as any complications arising from general or local anaesthetic, analgesic or other sedation during labour or delivery.[9, 10]

It is likely that the anaesthetic related mortality and morbidity at UTH were similar to that of other developing countries, but at the time of the study it was not possible to confirm or refute the assumption. These figures are important since they help to identify the reasons behind the avoidable complications. The identification of complications and anaesthetic factors associated with these complications would help in the formulation of a strategy specific to UTH and potentially to Zambia to prevent such avoidable mortality. Improvements to quality care of patients' perioperatively can only be enhanced once

anaesthetic related morbidity and mortality is studied. This study endeavored to explore this aspect. No similar study had been done in Zambia before.

2.0 Literature review

What is unknown on the topic at UTH

Perioperative complications during caesarean delivery are a major cause of maternal morbidity and mortality.[11] These complications range from surgical, patient associated and anaesthetic related.[12] There is no available data at the University Teaching Hospital, Lusaka, on anaesthetic related perioperative complications but anecdotal evidence suggests that it is high.

What is already known on this topic with regards to mortality globally

Complications of anaesthesia in the pregnant patient are known to be more common in Africa, and the third South African Confidential Enquiry into Maternal Deaths (CEMD) 2002-2004 reported anaesthesia to be one of the top four causes of avoidable deaths in pregnancy.[13, 14]

Every year about 250,000[14] African women die during pregnancy, delivery or the pueperium, but little is known about the causes. A two year retrospective study of 251 maternal deaths at UTH, Lusaka, Zambia,[15] showed that obstetric causes accounted for 42% of maternal deaths. Similarly an autopsy study of 171 maternal deaths at a tertiary referral centre in Mozambique,[16] found that 44% of maternal deaths were due to obstetric causes. Although it is impossible to extrapolate from this data, complications of anaesthesia are considered to play a part in this mortality. Out of 9833 operative procedures (91% under general anesthesia) in a study carried out in Zimbabwe, 22 anesthetic associated deaths were reported and 7 deaths were directly attributable to anaesthesia.[17, 18]

In the developing world, it can be stated with certainty that anaesthesia-related mortality is much higher than in the developed world. The Confidential Enquiry into Maternal deaths (CEMD) in South Africa, initiated in 1998 constitutes the best evidence for anaesthesia-related mortality in a low-resource environment. It reports 56 deaths attributable to anaesthesia versus 2 in the United Kingdom in its triennium 1999-2001.[19] While in the subsequent triennium (2002-2004), 62 of the total of 3296 maternal deaths were attributable to anaesthesia. Anaesthesia ranked as the seventh (7^{th}) most common direct

cause of maternal mortality. Accurate denominator data are unavailable. In the more recent triennium (2005-2007), 74 direct anaesthesia deaths were reported and they represent only 0.03% of all maternal deaths. These are much higher figures compared to those in the United Kingdom. Since 1985, maternal death rates attributable to anaesthesia in the United Kingdom have fallen to four (4) or less per million deliveries.[20] In the most recent report, anaesthesia was the eighth (8^{th}) most common direct cause of death (6 deaths from a total of 261 cases).[9] In a study involving 4097 pregnancy related deaths in the United States of America for a period of more than 10 years, 155 deaths were caused by anesthesia related complications. Death due to anesthesia in this same study published in 1997 was said to be the sixth cause of pregnancy related mortality in the United States. Most maternal deaths due to complications of anesthesia occurred during general anesthesia for caesarean section. However, regional anesthesia is not without risk.[21]

What is already known on this topic with regards to morbidity globally

Morbidity resulting from anaesthesia may be similar in the developing countries in Africa.Enohumah et al reported 1 case (0.05%) of aspiration of gastric contents and,4 cases (0.2%) of failed intubation from a study at a Nigerian Tertiary Hospital involving 2020 cases receiving a general anaesthetic out of 2323 caesarean deliveries.[22] While in Togo, Tomta et al in a study involving 95 caesarean deliveries done under general anaesthesia out of a total of 318 caesarean sections reported 3 cases (3.2%) of aspiration of gastric contents,1 case (1.1%) of hypoxaemia (oxygen saturation < 90%) and 1 case (1.1%) of failed intubation.[1]

In the CEMD in South Africa for the triennium 1999-2001, the most common cause of morbidity leading to death during general anaesthesia was failed intubation. There were 4 cases due to pulmonary aspiration, 21 patients due to high block levels during spinal anaesthesia. In the rest of sub–Saharan Africa, combined perioperative morbidity leading to mortality for caesarean section is high (1-2%), most deaths were avoidable and one-third of them were attributable to anesthesia-predominantly due to airway problems.[11, 23, 24]

In a study done at Harare Central Hospital by Mc Kenzie[12], 3 cases of failed intubation due to difficulty airway aspirated gastric contents and 1 case of high spinal block were recorded.[18] While Steven et al[14] in a study involving 14797 spinals reported 313 cases

(2.1%) being failed spinals and 9 cases (0.06%) being high spinal blocks with associated respiratory distress.

In a study in Western Australia, out of 1095 deliveries at King Edward Memorial Hospital for women, morbidity related to anesthesia reported the following:-36 cases were difficult intubations (3.3%), 4 failed intubations (0.4%), 8 cases regurgitated gastric contents (0.7%) and 1 case of confirmed pulmonary aspiration (0.1%).[25] Clearly failed airway management is among the most implicated factors contributing to anesthesia morbidity in the United Kingdom.[9,19,26] The risk of failed intubation is higher by an order of magnitude in pregnant women than in the general surgical population.[27,28,]

Observational studies of operative mortality in Zimbabwe [18] and Malawi [11] suggest that spinal is safer than general anaesthesia, but it is recognized that spinal anaesthesia was also associated with increased morbidity from high spinal block. South African data[29] tend to urge caution, as 9 of 28 anaesthetic-related deaths in 1998 occurred with the use of spinal anesthesia, individual data regarding frequencies with either high spinal block or total spinal block is lacking. While a study done in Benin at the University of Benin Teaching Hospital, showed that out of 179 cases done under spinal from 300 parturients recruited for the study, hypotension due to spinal was recorded in 22 cases (12.2%), 4 cases (2.2%) with high spinal showed respiratory distress and low arterial oxygen saturations <90% while 16 cases (5%) exhibited shivering.[30]

In Asia, a study by B. L.Sng et al revealed that spinal anesthesia though providing excellent anaesthesia and avoiding complications associated with general anaesthesia also could fail and may require conversion to general anaesthesia,[31] the study further showed that out of 800 parturients undergoing elective caesarean section under spinal anaesthesia, incidence of total failure of spinal requiring conversion to general anaesthesia was 0.5% (4 cases). Spinal anaesthesia can also result in hypotension and a study by Husaini and Russell [32] in the United Kingdom revealed that out of 40 cases of caesarean section under spinal anaesthesia, 29 (72%) became hypotensive following induction of spinal anaesthesia. Even though spinal anaesthesia is considered to be safer than general anaesthesia it may fail, and at Aga Khan University hospital in the United Kingdom, 14 cases (6.7%) from the same study required conversion to general anaethesia following a failed spinal technique.[33]

My study aims at describing the anaesthetic related complications during caesarean delivery at University Teaching Hospital in comparison with what has been found elsewhere within the region and globally.

3.0 Study justification

The frequency of anaesthetic-related complications during caesarean deliveries at UTH, Lusaka, is not known. This data is important to establish standards of practice in obstetric anaesthesia at UTH, Lusaka, and may be generalisable to other hospitals in Zambia and the region. The study aims to contribute to the broader literature on avoidable anaesthetic-related complications in sub-Sahara Africa. It is anticipated that such data would provide a basis for quality improvement of maternal mortality at UTH, which directly addresses one of the World Health Organization's Millennium Development Goals.[34]

4.0 Research question

What is the frequency of anaesthetic–related perioperative complications during caesarean delivery at the University Teaching Hospital (UTH)?

Chapter two

5.0 Objectives

5.1 General objective:

To determine the frequency of anaesthetic related perioperative complications during caesarean delivery at UTH.

5.2 Specific objectives:

1. To determine the demographic characteristics of patients presenting for caesarean deliveries at UTH.

2. To determine the prevalence of anaesthetic complications at UTH during caesarean deliveries

3. To determine avoidable anaesthetic complications that contributes to morbidity and mortality at UTH.

6.0 Research methods

6.1 Setting

University Teaching Hospital, Lusaka.

6.2 *Study site*

The study was conducted in Caesar theatre in the department of obstetrics and gynecology.

6.3 Target population

All parturients scheduled for caesarean section.

6.4 Study population

All those parturients that met the inclusion criteria

6.5 Study design

This was a prospective cross sectional study.

6.6 Inclusion criteria

All parturients who underwent an anesthetic procedure for emergency, urgent, expedited or elective caesarean delivery, as defined by:

6.5.1 General anaesthetic

6.5.2 Spinal anaesthetic

6.7 Exclusion criteria

All parturient who declined to join the study

6.8Duration of study

Six months of data collection were carried out from 12th January to 12th July, 2014

6.9 Sample size

The following prevalence formula was used to calculate sample size; based on the estimated complication rate of 20%(departmental monthly audit reviews 2014), with 5% confidence limits and 95% confidence interval, the sample size for the study was calculated to be 246 without 30 (15%) adjustment for loss of participants to the study.

$N=Z^2 \text{ X } P\ (1-P)/\ (E)^2$

Where

N=sample required

Z=Z statistic=1.96(95% CI)

P=expected prevalence 0.2(assuming regional complication rate of 20%)

E=confidence interval 0.05

Therefore $N= (1.96)^2 \text{ X } 0.2(1-0.2)/\ (0.05)^2=246$

6.10 *Sampling Method*

Convenience sampling method was used. All women presenting for caesarean delivery were invited to participate in the study. Enrollment occurred Mondays to Fridays and also on those weekends when the study investigator was on-call. Two theatre nurses assisted the investigator with patient consenting and data collection. Those women who met the inclusion criteria were recruited consecutively for a period of six months. Patients consented for the study pre-operatively.

6.11 data collection

A standardized data abstraction form (appendix 5) was used to obtain information from the patient files. Data collected was from the immediate preoperative period, intra-operative period and up to the time the patient left the recovery room postoperatively. No personal details that may help identify participants appeared on the data collection form. Identification numbers were used for data collection and entry purposes. All cases were reviewed by the principal investigator, who then gave an opinion as regards to the avoidability of the anaesthetic related complication.

6.12 Primary outcome 1

Composite end point of all anesthetic-related complications

6.13Primary outcome 2

Individual anesthetic complications, defined in Table 1**.**

Table1. Definitions of Anaesthetic-Related Complications

Complication	Definition
Hypotension	Drop of 20% in BP from baseline or a drop in systolic BP to <100mmHg
Failed intubation	Inability to intubate the trachea
Aspiration of gastric contents	Classified as possible or confirmed, and latter being defined by typical signs and symptoms, with or without bronchoscopic or X ray findings and with the exclusion of alternative diagnosis.
Conversion from spinal to general anaesthesia	Spinal attempted but general anaesthesia required
High spinal block	Respiratory suppression requiring intubation
Severe Hypoxemia	Pulse oximetry recording of less than 85% at any time
Anaesthetic mortality	Death under anaesthesia, as a result of anaesthesia or within the recovery room 3 hours of an anaesthetic.

Table 2.Significant co morbidities

Diabetes	-type 1 -type 2 -gestational
Respiratory disease	-asthma -tuberculosis
Hypertension	-chronic -gestational
Cardiac disease	-congenital heart disease -valvular disease
Neurological disease	Acute or chronic neurological loss
Other systemic disease	-HIV/AIDS -Chronic kidney dysfunction

6.14 Statistical Analysis

Data entry errors were checked using double entry checks by two people entering the data. Range and consistency checks were done. The data was stored on the data capture sheet in SPSS software and analyzed using the same software (SPSS version 21, IBM, Armonk, US). Descriptive analysis was performed and appropriate charts produced. Stepwise logistic regression was done to assess individual independent variables in relation to anaesthetic related complications during caesarean deliveries. All significant variables were included in the final multivariable logistic model. All tests were set at 95% confidence interval (CI) and a P- value of <0.05 was considered statistically significant.

7.0 Ethical considerations

Ethical approval was sought from University of Zambia Biomedical Research Ethics Committee (UNZABREC) with a given reference number of 010-11-13. Permission to conduct the study was given in January 2014. The purpose of the study was fully explained to all participants and a written informed consent was obtained from all of them. Patients' confidentiality was maintained. All data entry forms were identified by coded numbers only. Filled questionnaires were kept under lock and key with only individuals involved in the study having access.

Chapter Three:

Results

8.1 Demographic characteristics of the patients

The study consisted of a sample of 246 patients. Table 3 below presents a summary of the biographical characteristics of the patients. Forty-four (17.9%) were aged 15-21 years, 85 (34.6%) were aged 22-28 years, 79 (32.1%) were aged 29-35 years, and 38 (15.4%) were aged above 35 years. The youngest was aged 15 years, the oldest was aged 47 years, the average age was 28.28 with a standard deviation of 6.323. Thirty-three (13.4%) had a gestation period of less than 36 weeks while 213 (86.6%) had a gestation period of more than 36 weeks. One hundred and sixty-four (66.7%) had a class 1 ASA status, 66 (26.8%) had a class 2 ASA status; and 16 (6.5%) had a class 3 ASA status. One hundred and eighty-nine (76.8%) had a class 1 Mallampati; 44 (17.9%) had a class 2 Mallampati, 8 had a class 3 Mallampati; and 5 had a class 4 Mallampati.

Further results revealed that three (1.2%) patients had anemia of pregnancy with Hb less than 10g/dl, 21 (8.5%) patients had known hypertension prior to falling pregnant, 6 (2.4%) had known asthma, 2 (.2%) had known diabetes; and 1 (.4%) had known tuberculosis.

Table 3: demographic characteristics of women undergoing caesarean sections

Variable	Values	Frequency (n=246)	Percent(%)
Age	***15-21***	***44***	***17.9***
	22-28	***85***	***34.6***
	29-35	***79***	***32.1***
	36 and above	***38***	***15.4***
Gestation period	***Less than 36 weeks***	***33***	***13.4***
	Greater than 36 weeks	***213***	***86.6***
ASA status	***Class 1***	***164***	***66.7***
	Class 2	***66***	***26.8***
	Class 3	***16***	***6.5***
Mallampati	***Class 1***	***189***	***76.8***
	Class 2	***44***	***17.9***

	Class 3	***8***	***3.3***
	Class 4	***5***	***2.0***
Co morbidity	***Anaemia of pregnancy with Hb less than 10g/dl***	***3***	***1.2***
	Hypertensive prior to falling pregnant	***21***	***8.5***
	Asthmatic	***6***	***2.4***
	Diabetic	***2***	***.8***
	Tuberculosis	***1***	***.4***
	Other disease condition or none at all	***213***	***86.6***

Indications for and category of caesarean deliveries

Table 4 below reveals that 68 (27.6%) patients had previous caesarean section,79 (32.1%) had obstructed labour, 26 (10.6%) had pre eclampsia, 40 (16.3%) had fetal distress, 17 (6.9%) had ante partum hemorrhage; and 16 (6.5%) had other unspecified indications. The categories of Caesarean sections were: 79 (32.1% were emergencies; 107 (43.5%) were urgent; 36 (14.6%) were expedited or scheduled; and 24 (9.8%) were elective.

Table 4: Indication for and category of Caesarean deliveries

Variable	Values	Frequency (n=246)	Percent (%)
Indication for Caesar	Previous caesarean section	68	27.6
	Obstructed labour	79	32.1
	Pre-eclampsia	26	10.6
	Fetal distress	40	16.3
	Ante partum hemorrhage	17	6.9
	Others	16	6.5
Category of Caesar[38]	Emergency	79	32.1
	Urgent	107	43.5
	Expedited/scheduled	36	14.6
	Elective	24	9.8

Grade of anesthetist and surgeon attending to patients

Table 5 shows the grade of the medical staff who attended to the patients during the operation. A hundred and fifty-nine (64.6%) patients were attended to by a clinical officer anaesthetist (COA), 4(1.6%) patients were attended to by MMed 1(year 1 trainee in Anesthesia and Intensive care), 33 (13.4%) patients were attended to by MMed 2, 48 (19.5%) patients were attended to by MMed 3, and 2 (.8%) patients were attended to by a Specialist (Consultant anaesthetist). Further analysis revealed that 3 (1.2%) patients were operated on by an Intern, 59 (24%) patients were operated on by a Pg 1(year 1 postgraduate trainee in obstetrics and gynecology),91 (37.0%) patients were operated on by a Pg 2, 49 (19.90%) patients were operated on by a Pg 3, 16 (6.5%) patients were operated on by a Pg 4, and 28 (11.4%) patients were operated on by a Specialist(Consultant obstetrician).

Table 5: Grade of anesthetist attending to patients

Variable	*Value*	*Frequency(n=246)*	*Percentage (%)*
Grade of most senior anaesthetist	Clinical officer anaesthetist(COA)	159	64.6
	MMed 1	4	1.6
	MMed 2	33	13.4
	MMed 3	48	19.5
	Specialist	2	0.8
Grade of most senior surgeon	Intern	3	1.2
	Pg 1	59	24.0
	Pg 2	91	37.0
	Pg 3	49	19.9
	Pg 4	16	6.5
	Specialist	28	11.4

The anaesthetic complications during caesarean deliveries

Table 6 and 7 below shows the anesthetic techniques used and the outcomes. Spinal anaesthetic was used on 212 (86.2%) patients while 34 (13.8%) received general anaesthetic. All the 246 patients were alive at time of leaving the recovery room post operatively. There were 105 spinals requiring a single attempt at insertion; 74 spinals required a second attempt at insertion, 33 spinals required a third attempt at insertion. There were 6 failed intubation and 20 failed spinal techniques. With regard to hypotension, 172 (69.9%) patients experienced drop of more than 20% of baseline BP, and 74 (30.1%) patients experienced drop of less than 20% of baseline BP. Twenty (9.4%) patients had conversion from spinal to general anaesthesia. Six (3.1%) patients had high spinal block. Five (9.3%) patients had possible aspiration, 16 (6.5%) patients had severe hypoxemia intraoperatively (oxygen saturation less than 85%) while 7 (2.8%) patients had severe hypoxemia postoperatively It was further observed that 178 (72.4%) complication cases could have been avoided.

Table 6: Anesthetic techniques used

Variable	Value	Frequency (n=246)	Percentage (%)
Initial anaesthetic* technique	Spinal	212	86.2
	General	34	13.8
Final anaesthetic technique	Spinal	192	78.1
	General	54	21.9
Number of attempts of spinal	Spinal required 1 attempt at insertion	105	42.7
	Spinal required 2 attempts at insertion	74	30.1
	Spinal required 3 attempts at insertion	33	13.4

*N.B.20 patients were converted from spinal to general anaesthesia

Table 7: Related anaesthetic outcomes

Variable	*Value*	*Frequency(n*)*	*Percentage (%)*
Failed intubation n=54	Yes	6	11.1
	No	48	88.9
Hypotension n=246	Drop of more than 20% of baseline BP	172	69.9
	Drop of less than 20% of baseline BP	74	30.1
Conversion from Spinal to general anesthesia n=212	Yes	20	9.4
	No	192	90.6
High spinal block n=192	Yes	6	3.1
	No	186	96.9
Possible aspiration n=54	Yes	5	9.3
	No	49	90.7
Severe Intraoperatively hypoxemia n=246	Yes; Oxygen saturation less than 85%	16	6.5
	No; Oxygen saturation greater than 85%	230	93.5
Severe Postoperatively hypoxemia n=246	Yes; Oxygen saturation less than 85%	7	2.8
	No; Oxygen saturation greater than 85%	239	97.2

*N.B. frequency was varied in calculating the percentages as shown.

Table 8a and 8b provides a categorized summary of the complications that could have been avoided. Thirty-five (19.7%) of these cases were anaesthetist related; 19 (10.7%) were equipment related; 93 (52.2%) were drugs related; and 31 (17.4%) were organizational related.

8a **Were any of the complications avoidable n=246**	Yes	Frequency n=246	Percent (%)
		178	72.4
	No	68	27.6

8b

Factor	Frequency n=178	Percent (%)
Anaesthetic related -inadequate pre-operative pt preparation -lack of experience -poorly supervised anaesthetic trainee -lack of pre-loading pt with intravenous fluids -poor pt positioning during insertion of spinal -wrong dosing	35	19.7
Equipment related -lack of spinal needles -lack of different sizes of laryngoscope blades -poor lighting laryngoscopes -poorly functional pulse oximeter probes	19	10.7
Drug related -lack of anti acid prophylaxis drugs -lack of desired vasoconstrictors	93	52.2
Organisational related **-**inconsistencies in drug supplies and their quality -lack of consumables -lack of monitoring equipment -lack of trained personnel -shortage of staff -unavailability of blood products	31	17.4
Total	178	100

Table 9 has multiples of 9a, 9b, 9c, 9d, 9e and 9f showing multivariable analysis on factors influencing anaesthetic related complications during caesarean deliveries.

9a

	Failed intubation (n=54)	
	Yes(6), No(48)	
Variable	**OR (95% CI)**	**p-value**
Age		
15-21		
22-28	0.950[0.828-1.091]	0.471
29-36		
>36		
ASA		
Class 1		
Class 2	0.363[0.099-1.333]	0.127
Class 3		
Category of caesarean		
Emergent		
Urgent	0.689[0.253-1.877]	0.467
Expedited		
Elective		
Grade of anaesthetist		
COA		
MMed 1		
MMed 2	1.117[0.572-2.182]	0.842
MMed 3		
Specialist		
Grade of surgeon		
Intern		
Pg 1		
Pg 2	1.306[0.581-2.935]	0.519
Pg 3		
Pg 4		

Specialist		
Mallampati		
Class 1		
Class 2	0.282[0.105-0.755]	0.012
Class 3		
Class 4		

In this table 9a we have included sub categories for e.g. grade of anaesthetists, ASA class etc which have been omitted from later tables in order to provide greater clarity.

9b

Hypotension (n=246) Yes(172), N0(74)		
Variable	**OR (95% CI)**	**p-value**
Age	0.986[0.944-1.030]	0.527
ASA	1,197[0.772-1.855]	0.422
Category of caesarean	0.967[0719-1.299]	0.821
Grade of anaesthetist	0.979[0.790-1,214]	0.846
Grade of surgeon	1.306[0.776-1.182]	0.655
Mallampati	Ref 1.00	

9c

Conversion from spinal to general anaesthesia (n=212) Yes(20), No(192)		
Variable	**OR (95% CI)**	**p-value**
Age	1.055[0.976-1.140]	0.176
ASA	1.074[0.487-2.368]	0.859
Category of caesarean	0.920[0564-1.503]	0.740
Grade of anaesthetist	0.899[0.632-1.279]	0.554
Grade of surgeon	1.224[0.821-1.825]	0.321
Mallampati	1.00 Ref	

9d

Aspiration (n=54) Yes(5), No(49)		

Variable	OR (95% CI)	p-value
Age	0.962[0.830-1.115]	0.608
ASA	1.302[0.256-6.631]	0.751
Category of caesarean	5.540[0.665-46.168]	0.114
Grade of Anaesthetist	1.632[0.622-4.283]	0.320
Grade of surgeon	1.035[0.475-2.257]	0.931
Mallampati	1.00Ref	

9e

	Hypoxaemia(n=246) Yes(16), No(230)

Variable	OR (95% CI)	p-value
Age	0.986[0.910-1.068]	0.727
ASA	1.314[0.524-3.297]	0.561
Category of caesarean	1.112[0.632-1.958]	0.712
Grade of Anaesthetist	1.467[0.875-2.459]	0.146
Grade of surgeon	1.021[0.683-1.528]	0.918
Mallampati	1.00Ref	

9f

	High spinal block(n=192) Yes(6), No(186)

Variable	OR (95% CI)	p-value
Age	1.009[0.886-1.146]	0.890
ASA	0.729[0.221-2.412]	0.605
Category of caesarean	0.543[0.244-1.210]	0.135
Grade of Anaesthetist	1.336[0.606-2.946]	0.472
Grade of surgeon	0.776[0.433-1.392]	0.395
Mallampati	1.00Ref	

Chapter four

9.0 DISCUSSION

This study investigated the frequency of anaesthetic perioperative complications during caesarean deliveries at the University Teaching Hospital (UTH). Anaesthetic related complications included hypotension in 172 cases (69.9%), failed intubation in 6 cases (11.1%), possible aspiration in 5 cases (9.3%),high spinal block in 6 cases (3.1%), hypoxaemia intra operatively and postoperatively in 16 cases (6.5%) and 7 cases (2.8%) respectively. Twenty cases (9.4%) were failed spinal techniques which were converted to general anaesthesia.

I observed 246 parturients undergoing caesarean deliveries for various indications among which included obstructed labour and previous caesarean section scars as the commonest indications, 79 cases (32.1%) and 68 cases (27.6%) respectively. This observation tallies with the findings by Fenton et al in a study done in Malawi [11]. Obstructed labour cases occurred as the major presentation and were due to cephalo-pelvic disproportion, poor progress in either first stage or second stage of labour. It was important to collect such data before looking at anaesthetic related complications so that future studies in anaesthesia may relate to them. Caesarean section indications such as fetal distress 40 (16.3%), ante-partum hemorrhages 17 (6,9%) were treated as either emergencies belonging to category one 79 (32.1%), or urgent cases belonging to category two 107 (43.5%) requiring delivery within minutes to an hour.

There was no mortality recorded in my study. Unlike other studies which had longer durations, longer days of observations of patients postoperatively and larger sample sizes powered to pick up mortality, my study was only for six months with a smaller sample size of 246 and patients were only observed up to the time they were in the recovery room postoperatively for three hours. It is this limitation that has contributed to the observed result and hence future studies are needed with extended study duration and longer periods of patient observation postoperatively possibly for more than three days and if possible enlarging the sample size.

The study indicates that spinal regional technique is the most common method of anaesthesia being performed at UTH. It accounted for 212 cases (86.2%) of the procedures

performed initially compared to 34 cases (13.8%) done under general anesthesia. This again correlates with the current international standards of practice where regional anaesthetic technique is the anaesthetic of choice for caesarean deliveries.[9,21] Audit guidelines from Royal College of Anaesthetists in the UK suggest that 85% of emergency caesarean deliveries should be conducted under Regional anaesthesia.[33] It is worth stating that since the introduction of the MMed program in anaesthesia, the trend has changed and more than before most cases are being performed under spinal technique(departmental monthly audit reviews 2014).

Twenty (9.4%) of the spinal technique failed and the same number were converted to general anesthesia. Hence this conversion raised the percentage of cases performed under general anaesthesia to 54 (21%), leaving cases done under spinal anaesthetic to 192(78%). My study indicated a higher conversion rate to general anaesthesia as a result of failed spinal in comparison to the studies by Sng and Lim[31] 0.5%,Garry and Davies[35] 8% and Kinsella[37] 4.9%. While the conversion rate from my study was lower than that by Jenkins and Khan[36] 14.3%. Again the Royal College of Anaesthetists' guidelines suggests that the conversion rate from spinal to general anaesthesia should be less than 3% for emergency caesarean deliveries and less than 1% for elective caesarean deliveries.[33] The most likely cause of the failure identified was scarcity of appropriate intrathecal needles. There is often a shortage of equipment at UTH this includes specialized intrathecal needles. When these specialized needles are not available, then the needles from 20 gauges or 22 gauges intravenous canullae are sometimes used instead and it is possible that this could affect adequacy of the spinal anaesthetic. Differences in study designs and study populations may also contribute to the disparities.

Six (2.4%) parturients exhibited respiratory distress as a result of high spinal. Experience of heaviness of the chest and a feeling of breathlessness were some of the parturients complaints and mask ventilation was instituted and all of them responded well with it without requiring intubation. This result from my study again showed a higher incidence in comparison to only 4 cases (2.2%) from a study in Benin at the University of Benin Teaching Hospital[30]. Differences in dosages and study populations may again be the reason for the disparity.

The study indicates no associations between age of parturient and anaesthetic complications as well as gestational age and resulting complication. The mean age of 28.28 with a standard deviation of 6.323 is similar to the mean age of parturients found in a study done by Steven et al on complications of anaesthesia for caesarean delivery in the United States of America (mean age 27.8 with a standard deviation of 6.4).[14] My study showed 213 (86.6%) of parturients presenting for caesarean delivery at greater than 36 weeks gestation compared to 33 (13.4%) who presented at less than 36 weeks gestation. This is because the latter had conditions that required expedited deliveries such as Pre eclampsia, premature pre-labour rupture of membranes and others. My study reviewed some co-morbid conditions. Although asthma, diabetes and tuberculosis were rare, associated hypertension 21 (8.55) and HIV were the most common. Co-morbid conditions could offer anatomical as well as physiological challenges to the attending anaesthetist in terms of patient preparation pre operatively, drug interactions and their metabolism. My study was not powered to look at co-morbid conditions contributions to anaesthetic complications.

There were 6 (11.1%) failed intubations found in my study compared with 2 (0.6%) from a study done in Togo[7],and 4 (0.4%) from a study in Western Austraria.[25] The high rate of failed intubation found in my study compared to results from other studies could be attributable to different patient group, inadequate equipment, lack of supervision of junior and inexperienced attending anaesthetists. Nonetheless, the current initiative of beginning a MMed program in anaesthesia and the ongoing delivery of a SAFE obstetrics course will help solve the situation in the near future. All failed intubation cases in my study were managed with either ketamine or a benzodiazepine with face mask and laryngeal mask airway insertion. None showed signs and symptoms of aspiration.

My study further indicated 5 (9.3%) cases of possible aspiration compared to 3 (0.9%) in a study done in Togo [7], 1 (0.1%) in a study done in Western Australia out of 1095 caesarean deliveries. [25]The differences noticed could be as a result of different denominators used. From my study the denominator used was that for cases performed under general anaesthesia hence the higher possible aspiration result, while in the two comparative studies, the overall denominator of all caesarean deliveries performed under either regional or general anaesthetic were used in the calculation. This higher possible aspiration result observed from my study calls for measures to be put in place to reduce

the harmful effects of aspirated gastric contents in the airways. At UTH there is lack of standardized practice of giving parturients antacid prophylaxis prior to carrying out the caesarean delivery. Medications for acid prophylaxis are lacking in emergency theatre at the institution and these patients come as emergencies without having fasted.

Significant hypotension occured in 172 (69.9%) cases. Hypotension due to spinal anaesthesia was recorded in 162 cases (94%) and that due to general anaesthetic was seen in 10 cases (6%). Hypotension under spinal in my study is more frequent than that observed from a study in Benin, in which only 22 cases (12.3%) out of 179 done under spinal yielded hypotension,[30] and Husain and Russel[32] in their study of 40 patients undergoing caesarean deliveries under spinal anaesthesia reported 29 cases (72%) to have had hypotension. It is important to note that there are potential limitations to comparing these hypotension rates observed in my study to others. First, measurement has not been standardized, that is the attending anaesthetist may have used a smaller or bigger cuff on the patients. Secondly, I did not collect data on the use of vasopressors during the anaethetic. Although the institution lacks desired vasoconstrictors such as ephedrine, phenylephrine and metaraminol, adrenaline is often available and again it is entirely up to the attending anaesthetist to use it or not. Thirdly, I did not collect data on drug dosages used by different attending anaesthetist during administration of an anaesthetic. In short, I had not standardized the drug dosages to use either while doing a spinal or during general anaesthesia. Inspite of these limitations, I am of the view that hypotension rates found in my study provide evidence that this complication is much more frequent among parturients receiving an anaesthetic during caesarean delivery and future research is needed to elucidate the problem.

Overall 178 cases (72.4%) of the complications recorded from my study could have been avoided. The distribution of the characteristics of the avoidable complication was itemized as discussed.

My study indicates that 35 (19.7%) cases experienced complications; which could have been avoided if the attending anaesthetist had been diligent, prepared, experienced or supervised and anticipated their occurrence. Ninety-three (52.2%) of the complications were drug related and would have been avoided if inconsistencies in drug supply and availability at the institution was not an issue. It is important to note that at UTH, certain

drugs run out of stock for long periods or are just simply not available. For instance, 0.5% bupivacaine was in short supply occasionally during the study period, and during those times lignocaine and opiods were used by the attending anaesthetist for spinal anesthesia.

Thirty-one cases (17.4%) and 19 cases (10.7%) were organizational and equipment related contributing factors respectively. Lack of consumables, unavailability of blood products, lack of different sizes of cuffs, lack of spinal needles, poorly functional pulse oximeter probes, lack of different sizes of laryngoscope blades and poor lighting were some of the many challenges faced by the attending anaesthetist at my institution and this contributed largely to the avoidable complications identified. Some of them are similar to the avoidable anaesthetic complications found by Mc-kenzie in his study,[12] although from my study I could not attach figures to isolated complications since I did not record any mortality. At the same time no independent reviewer was used in the assessment of avoidability of the complications in my study, this is acknowledged as a limitation.

It is worth noting that 7 cases (2.8%) from my study had severe hypoxemia post operatively noted by the attending anaesthetist with a well functional pulse oximeter probe. This is concerning since the post operative environment at UTH is not well established; it lacks trained recovery room nurses, the room is not conducive for recovering post operative patients as it has no beds, oxygen sources, resuscitative equipment, drugs or monitors. Attention needs to be given towards establishing a dedicated recovery unit for emergency caesarean deliveries.

There was no statistically significant associations among patients age, ASA status, category of Caesarean section, grade of anaesthetist, grade of surgeons, anaesthetic technique and all anaesthetic related perioperative complications, ($p>0.05$) except Mallampati and failed intubation as $p<0.05$. However, future studies are needed to look solely into each specific complication as my study was not powered to do that.

10.0 STUDY LIMITATION AND STRENGTHS

10.1 study limitation

This study was not powered to compare individual complications. It had a short outcome period of only up to recovery room, potentially missing anaesthetic related morbidity and mortality after this period. True emergency indication for caesarean section may have

been under represented in the study as these patients had no time to give consent for study enrollment. The results of the study may not be generalisable to rural hospital practice where problems with equipment supply is thought to be a greater issue. No independent reviewer of cases was used to assess avoidability of anaesthetic complications in my study.

10.2 strengths of the study

Data was systematically collected with few omissions/missing entries. This is the first study within Zambia that has looked at anaesthetic related complications during caesarean deliveries.

11 CONCLUSIONS

My study reveals that there is a high rate of anaesthetic related complications at UTH. However, these complications are not associated with factors such as ASA class ,age of parturient, grade of anaesthetist and anaesthetic technique, but seem to be related to factors such as lack of equipment and drugs, organizational issues and possibly training of anaesthesia staff. Future research needs to revisit these issues with a focus on a robust analysis of the avoidability of complications.

12. RECOMMENDATIONS

1. Prophylactic anti-acid medication should be routine for all women undergoing caesarean section.
2. A larger study specifically powered to look at each individual complication, or multiple further studies focused on individual complications, are warranted to address their specific incidences.
3. There is need to increase capacity in recovery services of post caesarean section patients.
4. There is need to have standard monitoring equipment in both theatre and recovery room.
5. There is need to have consistency of consumable supplies plus others such as spinal needles, drugs
6. There is need for improved training of anaesthetists and, supervision of junior anaesthetist

7. There is need for promotion of targeted training for obstetric anaesthesia such as SAFE Obstetric course

REFERENCES

1. Ahmed Y. Obstetric problems in the adolescent Zambian mother studied at UTH, Lusaka, Zambia. Med J Zambia,1982: May-July;vol 3: 65-68

2. Michael S Avidan, Phillipa Groves, Margaret Blott. Low complication rate associated with CS under spinal anaesthesia for HIV 1-infected women on anti-retroviral therapy. Anesthesiology 2002; vol97:320-324

3. Onwuhafua P I,Onwuhafua A, Adze J.The challenge of reducing maternal mortality in Nigeria.Int Journal of Gynaecol Obstetric 2000;71: 211-213

4. Kampikahio A ,Irwig L M. Incidence and causes of maternal mortality in five Kampala Hospitals 1980-1986.East Afr Med J 1991; vol68: 624-631

5. Ujah I A O,Uguru V E,Aisien A O,SagayAS,Otubu J A M.How safe is motherhood in Nigeria? The trend of maternal mortality in a tertiary health institution. East Afr Med J 1999;76: 436-439

6. Sule-Odu A O.Maternal deaths in Sagamu,Nigeria. Int J GynaecolObstet 2000;69:47-49

7. A F Ouro-Bangna,Maman M D,K Tomta M D.Death associated with Anaesthesia. Tropical doctor Oct 2005; vol 35: 220-222

8. Reynolds F.Maternal Mortality-Anaesthesia in perspective.SOAP news letter 1993;24: 5-8

9. Lewis G. (ed). The Confidential Enquiry into Maternal and child health (CEMACH).Saving mothers lives reviewing maternal deaths to make motherhood safer 2003-2005,2007

10. Wee M Y K,Brown H,Reynolds F.The National Institute of clinical Excellence(NICE) guidelines for caesarean sections:implications for the anaesthetist.Int J ObstetAnaesth 2005;14:147-158

11. Heywood A J, Wilson I H, Sinclair J R. Peri operative mortality in Zambia. Annals of the royal college of surgeons of England 1989; vol 71: 354-358

12. McKenzie G. Mortality associated with anaesthesia at Zimbabwean teaching hospitals. South African medical journal 1996;vol86: 338-342

13. National committee on confidential enquiry into maternal deaths, saving mothers-report of confidential Enquiry into maternal deaths in SA 2002-2004

14. Steven L. Bloom, Catherine Y Spong,Steven J Weiner. Complications of Anesthesia for caesarean delivery.Int J Obstetric Gynaecol 2005;106: 281-287

15. Ahmed Y,Mwaba P, Chintu C et al. A study of maternal mortality at the University Teaching Hospital, Lusaka, Zambia: The emergency of TB as a major non obstetric cause of maternal death. Int J Tuberc Lung Dis 1999; vol3: 675-680

16. Menendez C, Romagosa C, Ismail M,et al. An autopsy study of maternal mortality in Mozambique: the contribution of Infectious diseases.Plos med 2008; vol 5: 44

17. Chobli. Reduce morbidity and mortality in anaesthetic developing countries; focus on obstetric surgery, Annal for Anaes Reanin 1999; vol18: 619-620

18. Andriamady Rasorimahandry, CL Rakotoarimanana, M Ranjalahy RJ. Maternal Mortality in the Maternity ward of Befelatanama,University hospital of Antananarivo.Int J Obstetric Gynecology 2000; vol29: 501-508

19. Lyons G. Saving mothers lives: Confidential Enquiry into Maternal and Child Health 2003-2005. Int J Obstetric Anaest 2008; vol 17: 103-108

20. Cooper G M & Mc Clure J.H, Anesthesia Chapter from saving mothers reviewing maternal deaths to make pregnancy safer. Brit J Anaes 2008; vol 100: 17-22

21. Joy L,Hawkins M D,Lisa M, Koonin M N. Anaesthesia-related Deaths During Obstetric Delivery in the United States,1979-1990.Anaesthesiology 1997;86:277-84

22. Enohumah K O &Imarengiaye CO. Factors associated with anaesthetic related maternal mortality in a tertiary hospital in Nigeria.Acta Aneasthesia scand 2006;vol 50: 206-210

23. Fenton PF,Whitty CJ & Reynolds F.Caesarean Section in Malawi; Prospective study of Early maternal and perinatal mortality.Brit Med J 2003; vol 327:587-590

24. McKenzie AG. Operative Mortality at Harare Central Hospital.1992-1994:An anaesthetic view. Int J Obst anaesthesia1998; vol 7: 237-241

25. N.J Mc Donnel,M J Paech,O.MClavis,K L Scott.Difficult and Failed Intubation in Obstetric Anaesthesia.University of Western Australia and Department of Anaesthesia and Pain Medicine 2008.

26. Ngan Kee WD. Confidential Enquiries into maternal deaths:50 years of closing the loop.Bri J Anaes 2005; 413-416

27. Barnado PD , Jenkins JG, Failed tracheal intubation in obstetric: a 6 yr review in a uk region. Anaesthesia 2000; vol 55: 690-694

28. Lyons G. Failed intubation .Six years experience in a teaching maternity unity. Anaesthesia1985; vol 40:757-762

29. Rout C.Maternal mortality and Anesthesia in Africa:A South African perspective. International journal of ObstetAnaest 2002;vol 11:77-80

30. Edomwonyi N.P, Osaigbovo P.E. Incidence of Obesity in Parturients scheduled for Caesarean, intra-operative complications, management and outcome. East African medical journal April 2006; vol 83: No. 4

31. Sng B.L,Lim Y,Sia A.T.H. An observational prospective cohort study of incidence and characteristics of failed spinal anesthesia for caesarean section. International journal of obstetric anaest 2009; vol 18: 237-241

32. S.W.Husaini, I.F.Russel. Volume Preload; Lack of effect in prevention of spinal-induced hypotension at caesarean section. International journal of obstetric anesthesia 1998;7:76-81

33. Royal college of Anaesthetist.Technique of Anaesthesia for caesarean section 2011.In Raising the standard,a compendium of Audit Recipes

34. Simwaka B N,Theobald S,Amekudzi Y P,Tolhurst R. Meeting Millenium Development Goals 3 and 5.BMJ 2005;331:708-709

35. Garry M,Davies S.Failure of regional blockade for caesarean section.Int J obstet Anaesth 2002;11:9-12

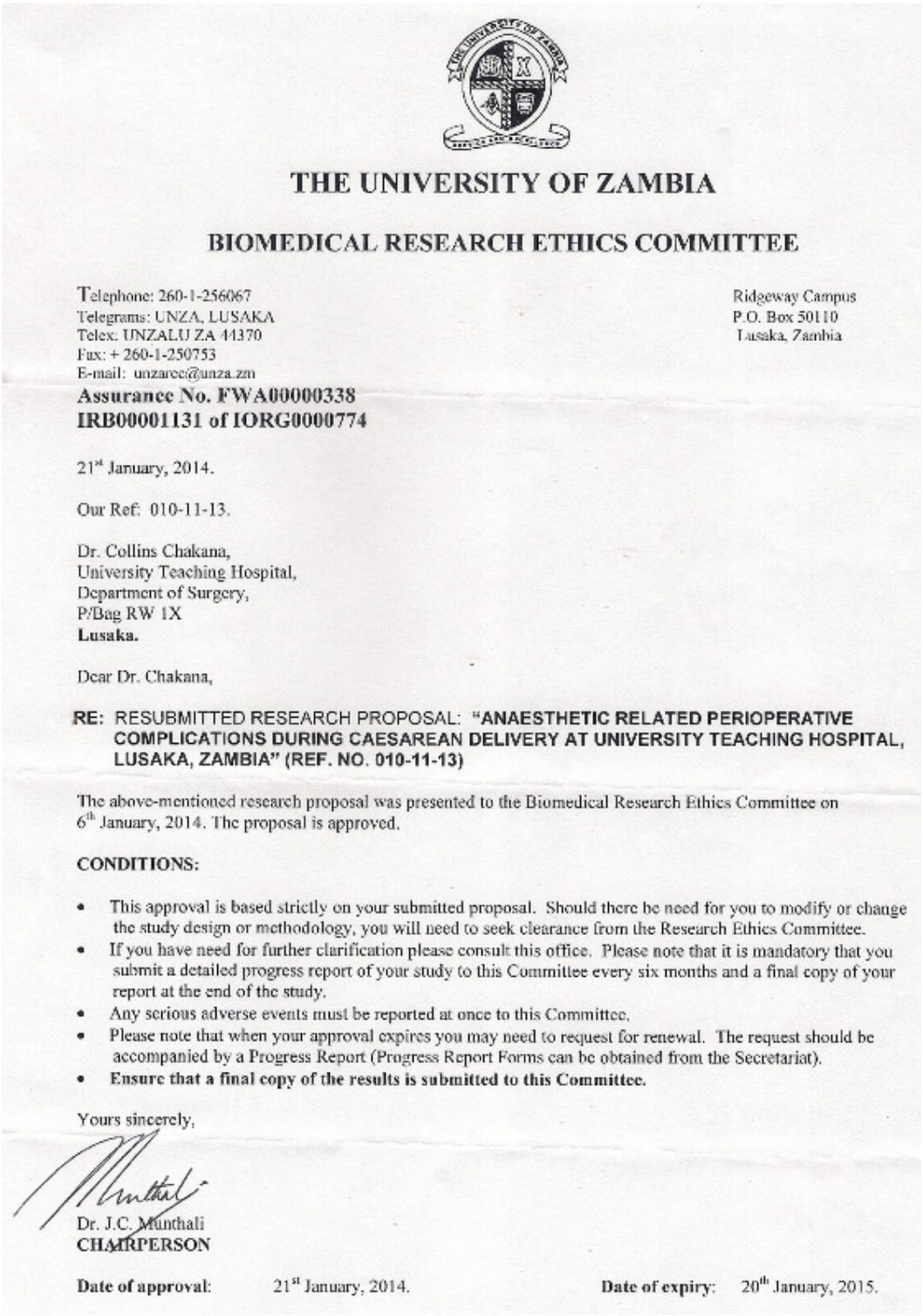
36. Jenkins J.G,Khan M.M.Anaesthesia for caesarean section;a survey in uk region from 1992 to 2002,Anaesthesia 2003;53:1114-8

37. Kinsella S.M. Aprospective audit of regional anaesthesia failure in 5080 caesarean sections,Anaesthesia 2008;63:822-832

38. Lucas D.N,Yentis S.M,Kinsella S.M et al.Urgency of Caesarean Section:A new classification.J.R.Soc med 2000;93:346-50

Appendix 1

UNZABREC



THE UNIVERSITY OF ZAMBIA

BIOMEDICAL RESEARCH ETHICS COMMITTEE

Telephone: 260-1-256067
Telegrams: UNZA, LUSAKA
Telex: UNZALU ZA 44370
Fax: + 260-1-250753
E-mail: unzarec@unza.zm

Ridgeway Campus
P.O. Box 50110
Lusaka, Zambia

Assurance No. FWA00000338
IRB00001131 of IORG0000774

21st January, 2014.

Our Ref: 010-11-13.

Dr. Collins Chakana,
University Teaching Hospital,
Department of Surgery,
P/Bag RW 1X
Lusaka.

Dear Dr. Chakana,

RE: RESUBMITTED RESEARCH PROPOSAL: **"ANAESTHETIC RELATED PERIOPERATIVE COMPLICATIONS DURING CAESAREAN DELIVERY AT UNIVERSITY TEACHING HOSPITAL, LUSAKA, ZAMBIA" (REF. NO. 010-11-13)**

The above-mentioned research proposal was presented to the Biomedical Research Ethics Committee on 6th January, 2014. The proposal is approved.

CONDITIONS:

- This approval is based strictly on your submitted proposal. Should there be need for you to modify or change the study design or methodology, you will need to seek clearance from the Research Ethics Committee.
- If you have need for further clarification please consult this office. Please note that it is mandatory that you submit a detailed progress report of your study to this Committee every six months and a final copy of your report at the end of the study.
- Any serious adverse events must be reported at once to this Committee.
- Please note that when your approval expires you may need to request for renewal. The request should be accompanied by a Progress Report (Progress Report Forms can be obtained from the Secretariat).
- **Ensure that a final copy of the results is submitted to this Committee.**

Yours sincerely,

Dr. J.C. Munthali
CHAIRPERSON

Date of approval: 21st January, 2014. **Date of expiry:** 20th January, 2015.

Appendix 2

UTH letter

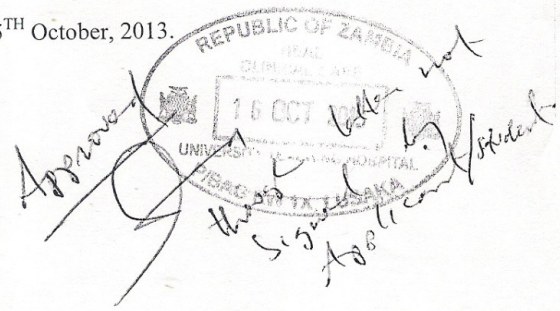
Department of Anaesthesia and Intensive C,

University Teaching Hospital,

Private Bag RW1X,

LUSAKA.

15TH October, 2013.



The Medical Superintendent,

University Teaching Hospital,

Private Bag RW1X,

LUSAKA.

Dear Sir

RE: APPLICATION FOR PERMISSION TO DO A STUDY IN CAESAR THEATRE OF UNIVERSITY TEACHING HOSPITAL

Reference is made to the above subject.

I am a 3rd year post graduate student in the department of surgery of The University of Zambia.

As part of fulfilment for the requirements of master of medicine in anaesthesia and intensive care I am required to do this research. The title of my study is **'Anaesthetic related perioperative complications during caesarean delivery at University Teaching Hospital Lusaka Zambia'.** The proposal has already been passed by UNZA graduates forum and I therefore need authorisation from your office to proceed with the study.

Thanking you in advance

Yours faithfully

DR. CHAKANA COLLINS

Appendix 3

GPPF Letter

THE UNIVERSITY OF ZAMBIA

SCHOOL OF MEDICINE

Telephone : +260211252641
Telegram: UNZA, Lusaka
Telex: UNZALU ZA 44370

P.O Box 50110
Lusaka, Zambia

Email: assistantdeanpgmedicine@unza.zm

15th October, 2013

Dr. Collins Chakana
Department of Anaesthesia
School of Medicine
UNZA
LUSAKA

Dear Dr. Chakana,

RE: GRADUATE PROPOSAL PRESENTATION FORUM

Having assessed your dissertation entitled **" Anaesthetic Related Perioperative Complications during Caesarean Delivery at the University Teaching Hospital (UTH), Lusaka, Zambia".** We are satisfied that all the corrections to your research proposal have been done. The proposal meets the standard as laid down by the Board of Graduate Studies.

You can proceed and present to the Research Ethics.

Yours faithfully,

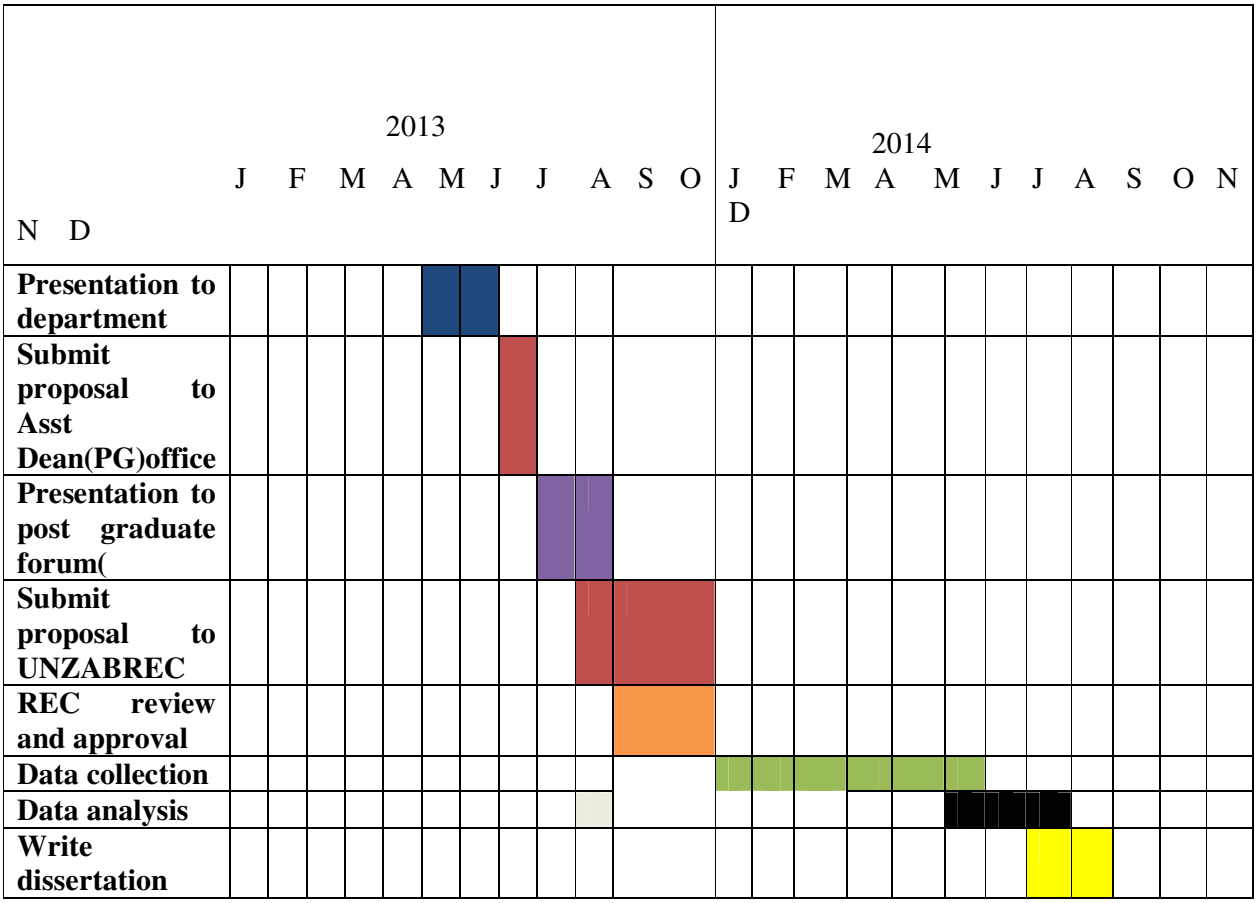
Dr. S.H. Nzala
ASSISTANT DEAN, POSTGRADUATE

CC: HOD, Anaesthesia

UNIVERSITY OF ZAMBIA
SCHOOL OF MEDICINE
16 OCT 2013
ASSISTANT DEAN (PG)
P.O. BOX 50110, LUSAKA

Appendix 4

8.0Time table



9.0 Budget

Stationary	K1,000
The University of Zambia Research Ethics Committee fees	K1,000
Research assistants	K1,500
Secretarial work	K1,000
Data entry and analysis	K4,000
miscellaneous	K4,000
Thesis preparation	K4,000
Total	**K16,500**

Funds shall be sourced from GRZ and self.

Appendix 5

q*uestionnairre*

Anaesthetic related perioperative complications during caesarean delivery at University Teaching Hospital, Lusaka, Zambia.

Participant ID(initials)…….

Please fill in appropriate space or tick or circle the number.

Preoperative Phase

1. Date…….
2. Patient's identification # .....
3. Patient's age…….
4. Gestational age…
5. ASA class : 1. *i 2. ii 3. iii 4. iv 5. v*
6. Mallampati: 1. *i 2. ii 3. iii 4. iv*
7. Co-morbidy condition,1.*anemia(Hb…….g/dl)* 2.*Hypertention* 3.*Asthma*, 4.*Diabetes* 5.*tuberculosis* 6.*others…*
8. Indication for c/s1.previous caesarean scar 2.obstruction 3.pre/eclampsia 4.fetal distress 5.APH 6.Others
9. Urgency for c/s: 1. Emergency *(category 1)* 2. *Urgent(category 2)* 3.*Expidited(category 3)* 4. *Elective(category 4)*

Intra-operative phase

10. Grade of most senior anesthetist/s: 1.*Clinical officer anaesthetist (COA)* 2.pg1 3.pg2 4.pg35.*Consultant*
11. Grade of most senior surgeon:1. *Intern* 2.pg1 3.pg2 4pg3 5.pg4 6. *senior registrar/consultant*
12. Anaesthetic technique: (1)*Spinal Anaesthesia (SA)* (2)*General Anaesthesia (GA)*

13. Number of attempts of neuraxial anaesthesia :*1 2 3 4(not applicable)*

14. Failed intubation: 1. *Yes* 2.*No 3.(not applicable)*
15. Failed spinal technique: 1.*Yes* 2.*No 3.(not applicable)*
16. Significant hypotension*Baseline Bp…….mmHg*

    1.less than baseline by 20%

    2.*not less than baseline by 20%*

17. Conversion from SA to GA: 1. *Yes* 2.*No 3(not applicable)*

18. High spinal block: 1.*Yes* 2.*No 3(not applicable)*
19. Acid aspiration: 1. *Yes* 2.*No 3(not applicable)*
20. Severe hypoxemia: 1. Yes SpO_2*<85% 2. No* SpO_2*>85%*
21. Critical incident*:-* *1. regurgitation 2.laryngospasm 3.bronchospasm 4.allergy 5.none*
22. Severe hypoxemia post op -*1.Yes<85% 2.No>85%*

23. Where any of the complications avoidable? *1. Yes 2.No*

24. If assessed as avoidable,what was the major contributing factor: *1.Anaesthetist-related 2.equipment-related 3.drugs-related 4.organizational 5.response not needed*

Post-operative phase

25. Alive at time leaving Recovery room post-op *1. Yes 2. No*

26. If died:

i. cause of death

ii. post-op time at which died

iii. Was the death anaesthesia-related? Yes/No

iv. If the death is assessed as anaesthesia related,which was the main contributing factor? 1.equipment-related 2.drugs-related 3.organisation-related

Appendix 6

Information Sheet

Participant **Information sheet**

Informed Consent Form for Patients with Anaesthetic related perioperative complications participating in the study.

This Research on anaesthetic related complications, which is any problems arising from general or regional anaesthetic during caesarean delivery, is being carried out by Dr Chakana Collins, a master's degree student in the department of Surgery as part of the requirement for his studies. Complications of anaesthesia during caesarean delivery is a challenge at UTH and your participation in this study will help the student and also help improve the care of patients who may encounter those problems. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

This consent form may contain words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them to me.

You will not be required to give any specimen to the researcher apart from the ones required for your routine care as they are not needed for this study. Do not be surprised that we chose you. We are asking for this kind of help from all patients admitted and are about to have a caesarean section. Your help is highly valued, especially because this is an important problem.Information will be obtained using your medical records. However, if additional information is required, questioning time will only take less than 10 minutes.

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Feel free not to answer questions that you deem personal orto

withdraw from the study at any time.If you choose not to participate all the services you receive at this hospital will continue and nothing will change.

We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up in a cabinet. It will not be shared with or given to anyone.

If you are agreeable to taking part in the study, you can sign the consent.

Principle Investigator: Dr Chakana Collins,
Department of Surgery,
University Teaching Hospital,
P/Bag RW1X,
Lusaka.
Mobile Phone No. +260977 662777

University of Zambia Biomedical Research Ethics Committee,

Ridgeway Campus,

P. O. Box 50110,

Lusaka.

Appendix 7

CONSENT FORM Part 2: Certificate of Consent

I have been invited to participate in a research about Anaesthetic related perioperative complications during caesarean delivery at UTH, Lusaka, Zambia.
I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study

Print Name of Participant_____

Signature of Participant _____

Date _____

Day/month/year

If unable to read and write

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ Thumb print of participant

Signature of witness _____

Date _____

Day/month/yea

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1. They will have to answer questions administered to them by heath care worker from a questionnaire.
2. The questionnaire will be administered during a quick pre operative assessment in theatre,peri-operatively and before leaving recovery room postoperatively.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participantPrint Name of Researcher/person taking the consent_____